

Remarks:

Reconsideration of the Application in view of the above amendments and following remarks is requested. Claims 15-22 and 55-60 are now in the case. Claims 15 and 55 have been amended. Claims 1-14, 23-54, and 61-73 have been canceled.

Applicants assert that the present amendments add no new matter to the Application as originally filed.

The paragraph beginning on page 166, line 15 has been amended to include the ATCC Patent Deposit Designation Numbers for the hybridomas recited therein. Basis for the amendment to add the ATCC Patent Deposit Designation Numbers can be found in the attached ATCC Deposit Receipts.

Basis for the amendment to Claims 15 can be found in the Application as originally filed, see e.g., page 2, lines 10-12. ✓

Applicants reserve the right to prosecute claims to cancelled subject matter in one or more continuing applications.

I. Objections to Claims (*regarding part 2. of the Office Action mailed 05/07/2007, "the Present Office Action"*)

a. Regarding Claims 8-13

The Examiner has maintained the objection to Claims 8-13. The Examiner has alleged that Claim 8, as previously amended, incorporates non-elected subject matter from Claim 1. Applicants respectfully disagree; however, to simplify matters under consideration and to expedite prosecution and allowance, Applicants have cancelled Claims 8-13. Therefore, the present objection is moot as applied thereto and Applicants respectfully request that the objection be properly withdrawn.

b. Regarding Claims 56 and 57

The Examiner has maintained the objection to Claims 56 and 57. Claims 56 and 57 depend to Claim 55, and the Examiner has alleged that Claim 55 contains non-elected subject matter. To simplify matters under consideration and to expedite prosecution and allowance, Applicants have canceled the subject matter in Claim 55 drawn to the non-elected species. Therefore, the present objection is moot as applied thereto and Applicants respectfully request that the objection be properly withdrawn. ✓

Applicants reserve the right to prosecute claims to the canceled species in one or more divisional Applications under 37 CFR 1.78(d)(1)(ii)(A) as recited in the Federal Register Vol. 72, No. 161, page 46732, Tuesday, August 21, 2007.

c. Regarding Claims 61-73

The Examiner has objected to Claims 61-73 as having incorrect status identifiers. Applicants have canceled Claims 61-73. Therefore, the present objection is moot as applied thereto and Applicants respectfully request that the objection be properly withdrawn. ✓

II. Rejections under 35 U.S.C. §103(a) (regarding parts 3.-5. of the Present Office Action)

a. Regarding the 35 U.S.C. §103(a) rejection under Busfield in view of Hopp et al. and in further view of Lok et al.

The Examiner has maintained the rejection of Claims 8-10, 12, 13, 15-18, 20, 21, 55-57, and 59 under 35 U.S.C. §103(a) as unpatentable over US Patent Application No. 02-0164689 (Busfield) in view of Hopp et al. (PNAS 78: 3824-3828, 1981) and in further view of Lok et al. (US Patent No. 5,965,704).

Applicants respectfully traverse. To show *prima facie* obviousness "the prior art reference (or references when combined) must teach or suggest all the claim limitations." See MPEP 706.02(k); MPEP 2143; and MPEP 2143.03 citing *In re Royka*, 490 F.2d 981 (CCPA 1974).

The Claims incorporate the element that the antibody should reduce or neutralize the activity of either IL-20 (SEQ ID NO:8) or IL-22 (SEQ ID NO:6). This element is not disclosed in the prior art references; and therefore, the Examiner has failed to show that the Claims are *prima facie* obvious.

not true
→ the proposed
one inherent
(p. 2nd #)

Applicants have previously presented the above argument; however, the Examiner has alleged that the element is inherently present in the prior art references.

Applicants respectfully traverse. To establish inherency, the Examiner must show that the missing element is **necessarily** present in the prior art. See MPEP 2112. The element that the antibody should reduce or neutralize the pro-inflammatory activity of either IL-20 (SEQ ID NO:8) or IL-22 (SEQ ID NO:6), is **not necessarily present in the prior art references**. The prior art references describe an antibody that specifically

binds to IL-22RA; however, an antibody that specifically binds to an antigen does not necessarily also reduce or neutralize the activity of the antigen.

It is well understood in the art that an antibody that specifically binds to an antigen does not necessarily also neutralize or reduce the activity of the antigen. This is because an antigen commonly has multiple epitopic regions where an antibody may bind; and if an antibody binds to an epitope that is outside or unrelated to a specific ligand-receptor binding domain, the antibody will specifically bind to the antigen, but it will not neutralize or reduce the activity associated with the specific ligand-receptor binding. *Maybe.*

To further support the assertion that an antibody that specifically binds to IL-22RA does not necessarily also neutralize IL-22RA cell proliferative activity, Applicants have attached a 37 CFR 1.132 affidavit of WenFeng Xu. The Xu affidavit affirms that **"It is well understood in the art that an antibody that specifically binds to an antigen does not necessarily also neutralize or reduce the activity of the antigen"**. See point 4 of the attached Xu Declaration Under 37 CFR §1.132. Moreover, the Xu affidavit presents a sampling of the assay results from Example 28, Dr. Xu notes that

Not all antibodies that specifically bind to IL-22RA necessarily neutralize IL-22RA activity. For example... several antibodies that specifically bind to IL-22RA do not significantly reduce the IL-22RA activity of up-regulating cell proliferation via binding to IL-22...

See point 5 and 6 of the attached Xu Declaration Under 37 CFR §1.132 (emphasis added).

In light of the arguments presented above and the attached Xu affidavit, Applicants respectfully request that the Examiner properly withdraw the present rejection.

b. Regarding the 35 U.S.C. §103(a) rejection under Busfield or Lok et al. in view of Hopp et al. and in further view of Chen et al.

The Examiner has maintained the rejection of Claims 11, 14, 19, 22, 58 and 60 under 35 U.S.C. §103(a) as being unpatentable over Busfield (US 2002/0164689A1) in view of Hopp et al. (Hopp, TP and Woods, KR, PNAS USA 78:3824-28, 1981) and in further view of Lok et al. (US Patent No. 5,965,702) and Chen et al. (Chen AM, Scott, MD, BioDrugs, 2001; 15(12):833-47).

Applicants respectfully traverse. The MPEP instructs that

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim dependent therefrom is nonobvious.

See MPEP 2143.03 *citing In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). In the arguments presented above, Applicants have shown that independent Claims 15 and 55, are non-obvious over either Busfield or Lok et al. in view of Hopp et al. Accordingly, the Claims dependent therefrom (including Claims 19, 22, 58, and 60) are likewise nonobvious over either Busfield or Lok et al. in view of Hopp et al. } No.

Therefore, Applicants respectfully request that the Examiner withdraw the current rejection of Claims 19, 22, 58, and 60, based on Busfield or Lok et al. in view of Hopp et al. and in further view of Chen et al.

III. Double Patenting

The Examiner has provisionally rejected Claims 8-22 and 55-60 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-22 and 55-60 of copending Application No. 11/356,499.

Upon an indication of otherwise allowable subject matter and in the event that these rejections are maintained for the pending Claims, Applicants will provide an appropriate response.

IV. Conclusion

On the basis of the above amendments and remarks, Applicants believe that each rejection has been addressed and overcome. Reconsideration of the application and its allowance are requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 434-3410.

Application Serial No.: 10/807,837


10

Response and Amendment dated: October 9, 2007

Response to Office Action dated May 7, 2007

It is believed that no other fee is due. However, in the event that another fee is due, please charge any fee or credit any overpayment to Deposit Account No. 26-0290.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read 'A. A. Schützer', with a stylized flourish at the end.

Aaron A. Schützer
Registration No. 60,106

Enclosures:

Declaration Under 37 CFR §1.132

4 ATCC Deposit Receipts

Customer No. 10117

ZymoGenetics, Inc